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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte YEM CHIN and JOHN GRIEGO

Appeal 2008-0548
Application 09/963,676
Technology Center 1600

Decided: April 30, 2008

Before, DEMETRA J. MILLS, ERIC GRIMES, and LORA M. GREEN, *Administrative Patent Judges*.

MILLS, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134. The Examiner has rejected the claims for obviousness. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

Representative claims follow.

27. Method for determining length of exposure of a tissue cutting device from a distal portion of a lumen of an endoscope catheter, which comprises:

providing said tissue cutting device with a plurality of radiopaque indicia located at radiologically measurable intervals along a length of said tissue cutting device;

deploying said tissue cutting device to be exposed from said distal portion of said lumen; and

radiologically determining the length of said tissue cutting device as deployed from said distal portion of said lumen.

29. Method of claim 28 wherein said cutting device is a needle knife and said radiopaque reference point is at the distal end of the catheter.

35. A catheter having at least one lumen, said catheter comprising:

a tissue cutting device disposed in said lumen, said tissue cutting device having a cutting member disposed for extension out of an opening in said lumen;

said tissue cutting device further disposed in said lumen for movement along said lumen to move said cutting member out of said opening;

at least one radiopaque indicia disposed on said tissue cutting device to move with said tissue cutting device in said lumen,

wherein the length of said cutting member is extended from said opening is a length said radiopaque indicia is moved in said lumen.

37. The catheter according to claim 35 wherein said cutting member is a needle knife.

38. The catheter according to claim 35 wherein a radiopaque indicia is disposed on said catheter as a reference point.

Cited References

Nebergall et al.	US 4,588,399	May 13, 1986
Banys et al.	US 5,425,376	Jun. 20, 1995
Pacetti	US 6,574,497 B1	Jun 3, 2003

Grounds of Rejection

1. Claims 27, 28, 31, 35-37, and 39 stand rejected under 35 U.S.C. § 103(a) as obvious over Banys in view of Pacetti.

2. Claims 29, 32, and 38 stand rejected under 35 U.S.C. § 103(a) as obvious over Banys in view of Pacetti and Nebergall.

DISCUSSION

Background

"This invention generally relates to [an] apparatus that is useful in performing diagnostic and therapeutic modalities in the biliary tree and more particularly to apparatus that is used in performing incisions within an endoscopic catheter for facilitating the diagnosis of gallstones in the bile duct and other portions of the biliary tree and the removal of such gallstones." (Spec. 1.)

1. Claims 27, 28, 31, 35-37, and 39 stand rejected under 35 U.S.C. § 103(a) as obvious over Banys in view of Pacetti. We select claims 27, 35 and 37 as representative of the rejection before us since Appellants have not separately argued the other individual claims in the Brief. 37 C.F.R. 41.37(c)(1)(vii).

The Examiner finds with respect to claims 27 and 35 that

> Banys teaches a method for determining a length of exposure of a tissue cutting device from a catheter/cannula by observing the tissue cutting device which is entirely made of radiopaque (col. 6, line 9), then deploying said cutting device to the tissue. The length of the exposure of the cutting device is related to the distance of which the cannula is withdrawn (col. 6, lines 3-10).

> Though Banys teaches the cutting device being radiopaque, he fails to teach the radiopaque material arranged as a plurality of radiopaque indicia at measurable intervals. However, as seen in Fig. 3 of Pacetti, it is known in the art to provide a cutting device (needle, see abstract) with a plurality of radiopaque indicia at measurable intervals (for example: 60, 62).

(Ans. 3-4.)

Pacetti further describes that a fluorine-containing marker may encompass the medical device wholly or partly and indicates that the device may include a biopsy needle. (Pacetti, col. 4, ll. 12-23.)

The Examiner concludes

> it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Banys to include a plurality of spaced radiopaque indicia because having said plurality of spaced radiopaque indicia would allow the practitioner to monitor the distal and proximal portion of the biopsy needle, which would provide better positional accuracy than a single radiopaque indicia (the needle). Also, the distal or proximal radiopaque indicia is fully capable of being used as a reference point, as in a leading indicia or trailing indicia. … Pacetti also discloses having more than two radiopaque indicia, as seen in Fig. 10.

(Ans. 4.)

When determining whether a claim is obvious, an examiner must make "a searching comparison of the claimed invention – *including all its limitations* – with the teaching of the prior art." *In re Ochiai*, 71 F.3d 1565, 1572 (Fed. Cir. 1995) (emphasis added). Thus, "obviousness requires a suggestion of all limitations in a claim." *CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003) (citing *In re Royka*, 490 F.2d

981, 985 (CCPA 1974)). Moreover, as the Supreme Court recently stated, "*there must be some articulated reasoning* with some rational underpinning to support the legal conclusion of obviousness." *KSR Int'l v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007) (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) (emphasis added)).

We find no error in the Examiner's prima facie case of obviousness. We find that the Examiner has provided evidence in the cited prior art of each of the claimed elements and has articulated a reason why one of ordinary skill in the art would have modified the catheter of Banys with the radiopaque indicia of Pacetti.

Appellants contend with regard to claim 35 that "Banys *et al.* does not disclose or suggest a catheter having a tissue cutting device that is disposed in a catheter lumen, said cutting device disposed for extension out of an opening of the catheter lumen." (Br. 10.) Appellants further argue that "Banys teaches away from a tissue cutting device in which the tissue cutting devise [sic] is disposed *within* the lumen of the catheter." (Br. 13.)

We are not persuaded by this argument. Banys indicates that, "[w]hen desired, the cannula can be withdrawn rearwardly from the needle, exposing the lateral opening." (Banys, col. 3, ll. 33-36.) Further the "[c]annula bore 54 is sized to fit over the needle 16 in a sliding relationship." (Banys, col. 5, ll. 14-16.) The lateral opening is preferably "near the distal end 26 of the needle 16." (Banys, col. 5, ll. 4-6.) "The distal end of the needle . . . can be radiopaque." (Banys, col. 3, ll. 37-38.) Thus, Banys describes a cutting device, lateral opening 28 with cutting edge 27, which is disposed for extension out of an opening of the cannula bore of a catheter lumen. (Banys,

col. 5, ll. 4-9; Fig. 2.) In other words, when the cannula bore is in a sliding position over the distal lateral opening with its cutting edge 27, the cutting device is within the lumen of the catheter.

Appellants argue that it is the sharp leading edge (56) of the cannula (44) which is considered to be the tissue cutting device, and thus Banys does not disclose or suggest a cutting device on the distal portion of a catheter or a cutting device within the catheter lumen because the sharp cutting edge of the cannula is outside the catheter lumen. (Br. 10, 13-14.) We disagree. As discussed above, the cannula bore is in a sliding position over the distal lateral opening with its cutting edge 27, and therefore a cutting device is within the lumen of the catheter.

Appellants argue that it is only the distal end of the cannula having a cutting edge in combination with cutting edge 27 at the distal end of the lateral opening 28 that provides the device capable of cutting tissue and that there is no evidence of record to show that cutting edge 27 is fully capable of cutting tissue on its own. (Reply Br. 2-3.) However, claims 27 and 35 do not exclude the cutting device or cutting member being a combination of elements. Claims 27 and 35 merely require a cutting device or a cutting member to be formed when an element is disposed from a lumen, and the cutting edge of the lateral opening meets this limitation.

With particular respect to method claim 27, Appellants further argue that Banys does not disclose or suggest a method for determining the length of exposure of a tissue cutting device from a distal portion of the catheter. (Br. 13.) As discussed herein, we have found that Banys describes that cutting edge 27 of the lateral opening 29 is at the distal portion of the

catheter. Banys describes that the "physician can maneuver the distal end of the needle 16, which can be radiopaque for ease of viewing, to place a sample of tissue within opening 28 of needle 16." (Banys, col. 6, ll. 3-10.) Pacetti discloses marker bands 60, 62 on a catheter tube or biopsy needle. (Pacetti, col. 4, l. 21; col. 9, l. 63 to col. 10, l. 4.) In view of the above, we agree that the Examiner has provided sufficient evidence to support a prima facie case of obviousness of claim 27. We are not persuaded by Appellants' rebuttal argument.

Appellants present separate arguments for claim 37 in the Brief. (Br. 15, Reply Br. 4.) During examination, claims are to be given their broadest reasonable interpretation. *In re American Academy of Science Tech Center*, 367 F.3d 1359, 1364 (Fed. Cir. 2004). Appellants argue that the biopsy needle of Banys is not a needle knife nor is it a device suggestive of a needle knife. (Reply Br. 4.) However, Banys describes a cutting edge 27 on the lateral opening of a needle, meeting the needle knife limitation under the broadest reasonable interpretation of the term. Appellants have presented no evidence to support that the needle having a cutting edge described in Banys is not a needle knife. Nor have Appellants particularly defined what is intended by the term "needle knife" in the Specification. In view of the above, we affirm the rejection of claim 37.

Appellants further argue that "Pacetti does not disclose or suggest a needle knife." (Br. 17.) However, the Examiner relies on Banys for the disclosure of a needle knife, not Pacetti. Non-obviousness cannot be established by attacking references individually where the rejection is based upon the teachings of a combination of references. *In re Merck & Co., Inc.,*

800 F.2d 1091, 1097 (Fed. Cir. 1986). The test of obviousness is "whether the teachings of the prior art, taken as a whole, would have made obvious the claimed invention." *In re Gorman*, 933 F.2d 982, 986 (Fed. Cir. 1991).

Further, Pacetti discloses that a fluorine-19 containing marker may be used on any medical device which may benefit from enhanced MRI visibility. (Pacetti, col. 4, ll. 11-17.) Banys describes that the distal end of the needle may be radiopaque for ease of radiographic viewing. Thus, we agree with the Examiner that it would have been obvious to one of ordinary skill in the art from the disclosures of Banys and Pacetti to include at least one radiopaque indicia disposed on a medical device which may benefit from enhanced MRI visibility including a tissue cutting device which is a needle knife.

In view of the above, the obviousness rejection is affirmed.

2. Claims 29, 32 and 38 stand rejected under 35 U.S.C. § 103 as obvious over Banys in view of Pacetti and Nebergall. We select claims 29 and 38 as representative of the rejection before us since Appellants have not separately argued claim 32. 37 C.F.R. 41.37(c)(1)(vii).

The Examiner contends with respect to claims 29 and 38 that

> Banys teaches using a radiopaque biopsy needle to determine the location of a cutting device from a cannula but does not specifically recite the cannula having a radiopaque material. However, it would be obvious to one of ordinary skill in the art to use a cannula having a radiopaque tip, such as the one taught by Nebergall, because in order to determine the location of the cutting device relative to the cannula, it would be necessary to use the cannula as a reference point. Since Banys teaches using fluoroscopy to monitor the needle, it

> would be obvious to provide a reference point that is also usable under fluoroscopy, such as a cannula with a radiopaque tip.

(Ans. 4-5.)

Appellants contend that, "Nebergell [sic] *et al*. does not remedy the deficiencies of Banys *et al.* or Pacetti." (Br. 18.) For the reasons discussed herein we find no deficiencies in the combination of Banys and Pacetti.

Furthermore, Appellants argue that "[w]ith respect to method claims 29 and 32, the biopsy needle would still not have any distance between the sharp leading edge of the cannula (44) and the edge of lateral opening 28 of the needle because the leading edge of the cannula is the cutting device." (Br. 18.)

The Examiner responds, arguing that "the operation of the device of Banys requires that the lateral opening 28 of the needle be exposed from the distal end of the cannula in order to receive a tissue to be sampled for biopsy. (Ans. 7.) The examiner concludes that

> one of ordinary skill in the art would have been motivated to provide a radiopaque indicia on the cannula because it allows the cannula to be used as a reference point in order to determine the distance between the lateral opening of the needle and the distal end of the cannula. This would allow a practitioner to visually verify that the lateral opening of the needle is spaced away from the distal end of the cannula.

(Ans. 7.) We find no error in the Examiner's argument.

Appellants argue with respect to claim 38 that Banys does not disclose or suggest a catheter having a tissue cutting device disposed in the lumen. (Br. 18.) We are not persuaded by this argument.

As discussed herein Banys describes that, "[w]hen desired, the cannula can be withdrawn rearwardly from the needle, exposing the lateral opening." (Banys, col. 3, ll. 33-36.) Further the cannula bore 54 is sized to fit over the needle 16 in a sliding relationship. (Banys, col. 5, ll. 14-16.) Thus, Banys describes a cutting device, the lateral opening 28 with cutting edge 27, which is disposed for extension out of an opening of the cannula bore from within a catheter lumen. (Banys, col. 5, ll. 4-9.)

Lastly, Appellants argue that "while Banys et al. does disclose the use of a radiopaque feature on the distal end of the needle, the purpose of the radiopaque feature is to align the needle with the tissue sample. It is not for determining how much of the needle is exposed outside the lumen of the cannula." (Br. 14.) Thus, Appellants argue that Banys "does not disclose or suggest method for determining the length of exposure of a tissue cutting device from a distal portion of a catheter as required by" the claims. (Br. 14.) Appellants further argue that Banys discloses a steel cannula which is itself radiopaque and thus there is no motivation to provide any radiopaque indicia on the radiopaque cannula of Banys. (Reply Br. 6.)

We are not persuaded by this argument. First, the motivation to combine references does not have to be identical to a patent applicant's to establish obviousness. *In re Kemps*, 97 F.3d 1427, 1430 (Fed. Cir. 1996). Therefore, it is not relevant that the purpose of radiopaque feature of Banys is to align the needle with the tissue sample and is different from Appellants' purpose of the radiopaque feature.

Furthermore, the evidence of record, Pacetti, establishes that it was known in the art to provide medical devices including catheters and biopsy

needles with contrast agents and markers to allow visualization (a reference point) during an interventional procedure such as to positioning of a catheter or stent at a desired location in the patient's vasculature. (Pacetti, col. 6, ll. 60 to col. 7, ll. 7; col. 9, ll. 59-61; col. 13, ll. 21-24.) Nebergall further evidences knowledge in the art of a cannula with a radiopaque tip to provide the precise location and orientation of the cannula tip relative to the patient's internal anatomy. (Nebergall, col. 2, ll. 25-29.) Thus, the evidence of record supports that it would have been obvious to one of ordinary skill in the art to include radiopaque markings on a medical device such as the cannula of Banys to provide the precise location and orientation of the device.

The obviousness rejection is affirmed.

SUMMARY

The obviousness rejections are affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED

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lp